GUIDANT

CARDIAC

RHYTHM

MANAGEMENT

Physician's Manual

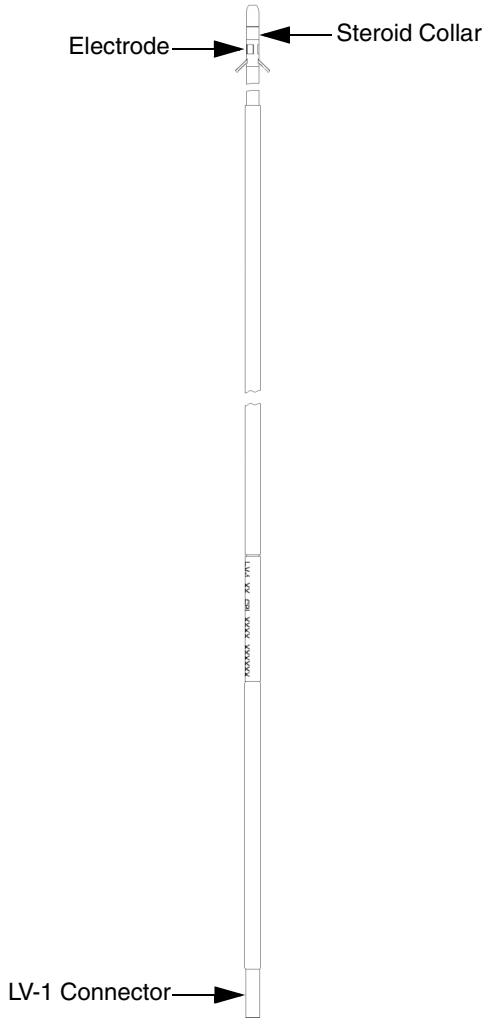
EASYTRAK®

Coronary Venous
Steroid-Eluting
Single-Electrode
Pace/Sense Lead

Models 4510/4511/4512/4513

RESTRICTED DEVICE: Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.

EASYTRAK® Lead
Models 4510/4511/4512/4513



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DEVICE DESCRIPTION

Guidant EASYTRAK® coronary venous, steroid-eluting, single-electrode pace/sense leads, Models 4510/4511/4512/4513, provide chronic pacing and sensing and are an over-the-wire design with a LV-1[1] connector. Placement is achieved by inserting the lead through the coronary sinus and placing it into a branch of the cardiac veins. The EASYTRAK lead is used in conjunction with a compatible Guidant heart failure device.

Indications

The Guidant EASYTRAK coronary venous, steroid-eluting, single-electrode pace/sense leads, Models 4510/4511/4512/4513, are transvenous leads intended for chronic left ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible Guidant heart failure device.

Contraindications

Use of the EASYTRAK lead is contraindicated in patients with a hypersensitivity to a nominal single dose of 0.7 mg of dexamethasone acetate drug.

Warnings

- When using a right ventricular (RV) pace/sense lead in conjunction with the EASYTRAK lead, it is recommended that a *polyurethane-insulated* lead be used. Failure to observe this warning could result in insulation damage of the RV lead, which can cause a periodic or continual loss of pacing, or sensing, or both.
- Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both.
- The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by leakage currents.
- Line-powered equipment used in the vicinity of the patient must be properly grounded.

- The lead connector must be insulated from any leakage currents that could arise from line-powered equipment.
- The lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, or lead dislodgment (Page 11).

Precautions

- The lead and its accessories are intended only for one-time use. Do not reuse.
- Prior to implantation of this lead, confirm lead/pulse generator compatibility by calling Guidant Technical Services at the telephone number on the back cover of the manual.
- It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of a low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the *Physician's Desk Reference*.
- Defibrillating equipment should be kept nearby for immediate use during the implantation procedure.
- Refer to the *Lead Evaluation* and *Implantation* sections of this manual for cautions specific to handling, implanting, and testing the EASYTRAK lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient.

ADVERSE EVENTS

Forty-nine lead-related adverse events were reported during the clinical investigation of the EASYTRAK coronary venous single-electrode pace/sense lead among the 448 patients who were implanted with an EASYTRAK lead. Twenty-seven procedure-related adverse events were reported among the 517 patients who underwent the implant procedure for an EASYTRAK lead. The overall lead-related adverse event rate was 13.9% [95% CI (10.9 - 16.9%)].

Observed Adverse Events

Table 1 reports lead-related adverse events and Table 2 reports procedure-related adverse events observed during the VENTAK CHF/CONTAK CD Biventricular Pacing Study.

Table 1. EASYTRAK Lead-related Adverse Events (n = 448)

Adverse Event	# of pts (n = 448)	% of pts (95% CI)
Loss of capture/lead dislodgment	29[1]	6.5% (4.2–8.8%)
Ventricular oversensing	10	2.2% (0.9–3.6%)
Extracardiac stimulation	8	1.8% (0.6–3.0%)
Insulation breach	2	0.4% (0.0–1.1%)

1. Twenty five events were successfully corrected in a repeat procedure.

Table 2. EASYTRAK Procedure-related Adverse Events (N = 517)

Adverse Event	# of pts (N = 517)	% of pts (95% CI)
Transient AV block	7	1.4% (0.4–2.4%)
Coronary venous dissection	5	1.0% (0.1–1.8%)
Coronary venous perforation	5	1.0% (0.1–1.8%)
Transient renal failure	4	0.8% (0.0–1.5%)
Pericardial effusion	2	0.4% (0.0–0.9%)
Finishing wire left in lead	1	0.2% (0.0–0.6%)
Right ventricular lead dislodgment	1	0.2% (0.0–0.6%)
Guide wire fracture	1	0.2% (0.0–0.6%)
Hypotension due to blood loss	1	0.2% (0.0–0.6%)

Potential Adverse Events

Based on the literature and lead implant experience, the possible physical effects from implantation of an EASYTRAK lead system are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Breakage/failure of implant tools
- Cardiac tamponade
- Chronic nerve damage
- Conductor coil fracture
- Death
- Elevated pacing thresholds
- Erosion/extrusion
- Extracardiac stimulation (eg, phrenic, diaphragm, chest wall, pocket)
- Fibrotic tissue formation (eg, keloid formation)
- Formation of hematomas or cysts
- Inappropriate therapy (eg, shocks, ATP, pacing)
- Incomplete lead connection with pulse generator
- Infection
- Lead displacement/ dislodgment
- Lead insulation break or abrasion
- Lead tip deformation and/or breakage
- Local tissue reaction
- Myocardial trauma (eg, cardiac perforation, irritability, injury)
- Oversensing/undersensing
- Pneumothorax
- Prolonged exposure to fluoroscopic radiation
- Random component failures
- Renal failure from contrast media used to visualize coronary veins
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thrombosis/thromboemboli
- Venous or coronary venous occlusion
- Venous or coronary venous trauma (eg, perforation, dissection, erosion)

CLINICAL TRIAL

The following is a summary of findings on the EASYTRAK lead observed during the VENTAK CHF/CONTAK CD Biventricular Pacing Study.

Implant Data

There were 517 patients enrolled in the VENTAK CHF/CONTAK CD Biventricular Pacing Study who underwent an implant procedure for an EASYTRAK coronary venous single-electrode pace/sense lead. The outcome of the EASYTRAK lead implant procedures is shown in Table 3.

Table 3. Outcome of EASYTRAK Lead Implant Procedures (N = 517)

Outcome	Patients	%
Implanted	448	86.7%
Not implanted, anatomic considerations[1]	40	7.7%
Not implanted, lead dislodged while removing guide catheter	13	2.5%
Not implanted, adverse event related to lead placement[2]	6	1.1%
Not implanted, inadequate pacing thresholds	6	1.1%
Not implanted, adverse event unrelated to lead placement[3]	2	0.4%
Not implanted, extracardiac stimulation	1	0.2%
Not implanted, reason not stated	1	0.2%
Total	517	100%

1. Inability to access the coronary sinus or inability to advance the lead.
2. Coronary sinus dissection/perforation or transient AV block.
3. Inability to place atrial pace/ sense lead and venous perforation during subclavian vein puncture.

Clinical Investigation

The lead study was a nonrandomized study comparing the performance of the EASYTRAK lead to criteria established prospectively. The objective of this investigation was to demonstrate the safety and effectiveness of the EASYTRAK lead. The EASYTRAK lead was successfully implanted in 448/517 (86.7%) of patients in whom an EASYTRAK lead implant was attempted. The mean implant duration of the study in the 448 patients who received the EASYTRAK lead was 14.8 months (range: 0 to 27.1 months) with a cumulative implant duration of 548 patient-years. Demographic information on all 517 patients studied is shown in Table 4.

Table 4. Demographic information on all Patients (N = 517)

Characteristic	Patients	%
Gender Male Female	 436 81	 84% 16%
Age at Implant (years)	66 ± 11	
Mean LVEF + Standard Deviation (%)	21 ± 6	
Etiology of Cardiomyopathy Ischemic Non-ischemic	 355 162	 69% 31%
NYHA Classification II III IV	 177 296 44	 34% 58% 9%

The EASYTRAK lead pacing threshold was measured with a CONTAK CD heart failure device at 0.5 ms pulse width. The EASYTRAK R-wave amplitudes and lead impedance were also measured with the CONTAK CD heart failure device in a biventricular lead configuration (from the EASYTRAK lead and right ventricular lead connected in parallel). Table 5 shows the lead measurements by follow-up period. Values are expressed as mean ± standard deviation.

Table 5. Lead Measurements by Follow-up Period

Time Postimplant	LV Pacing Threshold (V)	BV R-wave Amplitude (mV)	BV Lead Impedance (Ω)
Implant	1.8 ± 1.2	10.0 ± 5.1	340 ± 46
2 weeks	2.1 ± 1.4	9.1 ± 4.4	331 ± 44
1 month	1.8 ± 1.4	9.7 ± 4.4	345 ± 46
4 months	1.7 ± 1.2	9.9 ± 4.4	352 ± 46
7 months	1.9 ± 1.4	9.7 ± 4.4	351 ± 52
13 months	1.9 ± 1.3	9.9 ± 4.5	352 ± 49

The mean chronic (> 12 months) pacing threshold (0.5 ms pulse width) of the EASYTRAK lead was 1.9 ± 1.3 V, mean chronic biventricular R-wave amplitude was 9.9 ± 4.5 mV, and mean chronic biventricular lead impedance was 352 ± 49 W.

Clinical Summary

The EASYTRAK coronary venous lead can be safely placed in the coronary venous vasculature. Chronic pacing thresholds, R-wave amplitude, and lead impedance all exceeded prospectively defined limits and remain stable beyond two weeks.

Warranty

Guidant Corporation does not warrant or guarantee its EASYTRAK leads. Please see the enclosed Lead Information card for further information. For additional copies, please contact Guidant Corporation at the address on the back cover of this manual.

Refer to the Contraindications, Warnings, Precautions, and Adverse Events sections of this manual for information concerning the performance of this device.

DEVICE FEATURES

Detailed Device Description

Features of the EASYTRAK lead include the following:

- **Over-The-Wire Lead Design:** The lead design consists of an open-lumen conductor coil that tracks over a 0.014-in (0.36-mm) diameter guide wire.
- **Steroid:** The distal end contains a nominal dose of 0.7 mg dexamethasone acetate contained in a silicone rubber collar. Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at implant.
- **Slotted-Ring Single Electrode:** The slotted-ring electrode provides a pacing and sensing surface by providing tissue contact in the coronary venous system.
- **Pace/Sense Configurations:** The EASYTRAK lead offers various pace/sense configurations depending upon the programming options of a Guidant compatible heart failure device.

- **Distal Tip:** The distal tip is protected by molded silicone rubber. This protection allows for lead advancement through the coronary venous system.
- **Tined Electrode Fixation:** Two silicone tines, located proximal to the pace/sense electrode, provide passive fixation of the lead after surgical placement.
- **Lead Body:** The distal portion of the lead body is 4.8 Fr in diameter and consists of a trifilar coil that provides a conductive pathway. The conductor is sheathed in silicone insulation. In addition, the silicone rubber is covered with a polyurethane protective sleeve.
- **LV-1 Connector:** The LV-1 connector is 6 Fr in diameter. This allows the guiding catheter to be removed over the connector after lead placement.

LEAD EVALUATION

Implant Information

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

The EASYTRAK lead is not designed, sold, or intended for use except as indicated.

Items Included

Items packaged include the following:

- (1) EASYTRAK Lead
- (2) EASYTRAK Finishing Wires
- (2) Suture Sleeves
- (1) Vein Pick
- Literature Packet

Instructions in the lead manual should be used in conjunction with other resource material including the applicable Guidant heart failure device physician's manual and instructions for use on any implant accessories.

Additional Implant Tools

The following is a list of interventional devices used for implanting the lead; but not packaged with the lead:

- Guiding catheter, 8 Fr or larger, minimum 0.087-in (2.2-mm) inside diameter, that is intended for accessing the coronary venous system
    - Guide wire, 0.032–0.038-in (0.81–0.97-mm) diameter (optional), that is intended for use in the coronary venous vasculature
    - Deflectable tip mapping catheter, 6 Fr (optional), that is intended for use in the coronary sinus ostium
- Standard occlusion balloon, 6 Fr, that is intended for use in obtaining venograms by occluding the coronary sinus
- Guide wire, 0.014-in (0.36-mm) diameter, and torque device that is intended for use in the coronary venous system
- Implant accessories

Opening Instructions

The outer package and sterile tray should be opened under clean conditions. To ensure sterility, the sealed inner sterile tray must be opened using accepted aseptic technique by scrubbed, masked personnel. The sterile tray is opened by peeling back the cover.

Sterilization

Guidant sterilizes the lead and accessories with ethylene oxide gas (EtO) before final packaging. When they are received, they are sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead or accessories. Instead, return the lead to Guidant at the address on the back cover of this manual.

Surgical Preparation

Instrumentation for heart monitoring, imaging (fluoroscopy), external defibrillation, and pacing threshold and sensitivity measurements should be available during implantation. The

sterile field should be large enough to accommodate the use of the guide wires. Sterile duplicates of all implantable items should also be available for use if accidental damage or contamination occurs. Always isolate the patient from potentially hazardous leakage current when using electrical instrumentation.

Nominal lengths of the leads are as follows:

Model	4510	4511	4512	4513
Length	65 cm	72 cm	80 cm	90 cm

Selection of the lead length appropriate to the patient's cardiac anatomy is a matter of medical judgment.

Lead Accessories

The following items are packaged in the lead tray and are also available from Guidant as accessory items:

Vein Pick

The vein pick is a sterile, disposable, nontoxic, nonpyrogenic, plastic device designed to assist placement of the guiding catheter into the vein.

To use the vein pick during a cutdown procedure, isolate and open the selected vein using an appropriate instrument. Introduce the point of the vein pick via this incision into the lumen of the vein. With the point of the vein pick facing in the direction of the desired guiding catheter passage, gently raise and tilt the pick. Pass the guiding catheter under the vein pick and into the vein.

CAUTION: The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure.

EASYTRAK® Finishing Wire

The EASYTRAK finishing wire is designed to stabilize the positioned lead during guiding catheter removal. The lumen of the lead is tapered at the distal end. When the finishing wire is fully inserted, the reduced lumen diameter acts as a stop for the wire, stabilizing the lead movement within the vein.

Note: *The finishing wire MUST BE REMOVED before con-*

necting the lead to the pulse generator.

Suture Sleeve (Attachable)

The attachable suture sleeve is an adjustable, tubular reinforcement positioned over the outer lead insulation. It is designed to secure and protect the lead at the venous entry site after lead placement. Using a suture sleeve reduces the possibility of structural damage caused by suturing directly over the lead body.

CAUTION: Do not suture directly over the lead body, as this may cause structural damage. Use the suture sleeve to secure the lead at the venous entry site.

Handling the Lead

Observe the following when handling the lead:

WARNING: The lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, or lead dislodgment.

CAUTIONS:

- Do not wipe or immerse the distal lead tip in fluid prior to implant. Such treatment will reduce the amount of steroid available when the lead is implanted.
- Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.
- The conductor insulation is silicone rubber, which can attract particulate matter, and therefore must always be protected from surface contamination.

IMPLANTATION

Inserting the Lead

The lead may be inserted using one of the following two methods:

Via cutdown through the left or right cephalic vein.

Only one incision over the deltopectoral groove is required to

insert the guiding catheter through the cephalic vein. The endocardial lead is inserted into the right or left cephalic vein in the deltopectoral groove.

The vein pick packaged with this lead can be used during a cutdown procedure to aid insertion of the guiding catheter into the vein. Before inserting the guiding catheter, see the section, "*Lead Accessories*" for instructions on using the vein pick.

Percutaneously or via cutdown through the subclavian vein or internal jugular vein—typically the left subclavian or right internal jugular vein.

A subclavian introducer set is available from Guidant for use during percutaneous lead insertion.

CAUTION: When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage or chronic dislodgment to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle. It is important to observe these implant precautions to avoid clavicle/first rib damage or chronic dislodgment to the lead. It has been established in the literature that lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament.[2]

Leads placed by percutaneous subclavian venipuncture should enter the subclavian vein, where it passes over the first rib (rather than more medially), to avoid entrapment by the subclavius muscle or ligamentous structures associated with the narrow costoclavicular region.[3] Guidant recommends introducing the lead into the subclavian vein near the lateral border of the first rib.

The syringe should be positioned directly above and parallel to the axillary vein to reduce the chance that the needle will contact the axillary or subclavian arteries or the brachial plexus. Use of fluoroscopy is helpful in locating the first rib and

in guiding the needle. The steps below explain how to identify the skin entry point and define the course of the needle toward the subclavian vein where it crosses the first rib.

1. Referring to Figure 1, identify points St (sternal angle) and Cp (coracoid process).

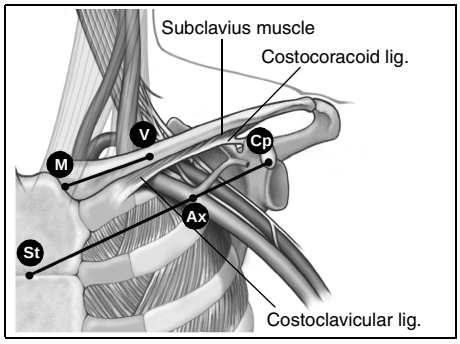

Figure 1. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).
3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.
4. Press a thumb against the index finger and project one or two centimeters below the clavicle to shield the subclavius muscle from the needle (when hypertrophy of the pectoralis muscle is apparent, the thumb should project about two centimeters below the clavicle because the subclavius muscle should be hypertrophied as well) (Figure 2).

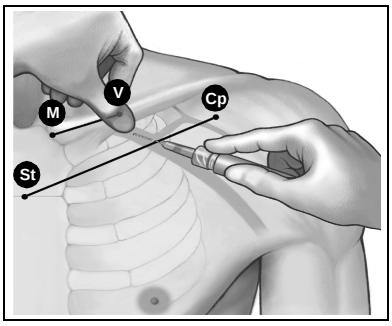

Figure 2. Location of thumb and needle entry.

5. Feel with the thumb the pressure from the passage of the needle through the superficial fascia; direct the needle deep into the tissues toward the subclavian vein and the underlying first rib. Fluoroscopic guidance will reduce the chance that the needle would pass below the first rib and into the lung.

CAUTION: When implanting the lead via a subclavian puncture, allow slack in the lead between the suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region.

Positioning the Lead

Positioning the lead includes the following steps:

1. ***Insert a guiding catheter*** into the ostium of the coronary sinus to provide a path for lead placement.
2. ***Obtain a venogram*** to visualize the coronary venous system.
3. ***Place the lead*** through the guiding catheter in the coronary venous system by advancing the lead over a guide wire.

Referring to Figure 3, the lead is introduced into the coronary venous system through the ostium of the coronary sinus and advanced into its tributaries. The coronary sinus and its tributaries include the great cardiac vein, middle cardiac vein, left

posterior vein, and left marginal vein. All cardiac veins are potential sites for implantation of the EASYTRAK lead. Variability in patient anatomy may preclude placement in one or more of the suggested sites.

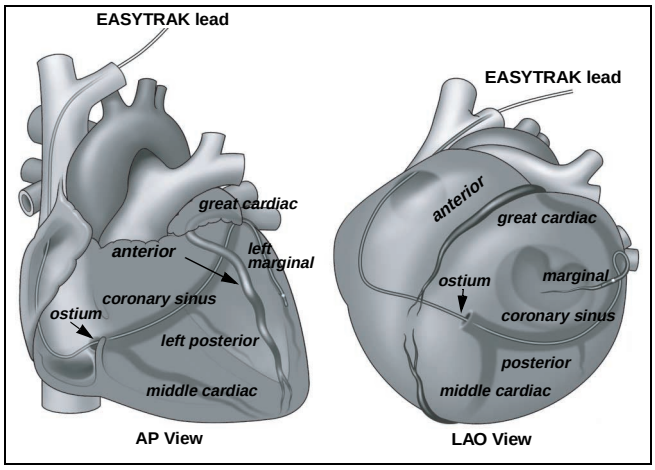

Figure 3. Anterior Posterior (AP) and Lateral Anterior Oblique (LAO) View of the Coronary Venous System.

Note: *It is recommended that a venogram be performed to determine the patient's cardiac anatomy. Any preexisting condition of the patient, eg, coronary stent or coronary artery bypass graft (CABG), should be taken into consideration while using proper medical judgement to determine the best lead implant site.*

Inserting the Guiding Catheter

Recommended methods for finding the coronary ostium include but are not limited to the following: **a)** placing a guide wire 0.032–0.038-in (0.81–0.97-mm) diameter in the ostium first and then following the guide wire with the guiding catheter or **b)** inserting a 6 Fr (or smaller) deflectable tip mapping catheter through the guiding catheter and then into the ostium.

Notes:

- *Prior to inserting the lead into the guiding catheter, the 0.032–0.038-in (0.81–0.97-mm) diameter guide wire or the deflectable tip mapping catheter must be removed.*
- *It is recommended that the guiding catheter be placed first, prior to the introduction of any leads into the heart. This will help prevent possible lead dislodgments caused by locating the ostium of the coronary sinus with the guiding catheter.*

Obtaining a Venogram

CAUTION: Risks associated with this procedure are similar to any other catheterization procedure in the coronary sinus. Some patients can have a physical intolerance to different types of contrast agents. If this is known in advance, the physician should select an appropriate agent.

Once the guiding catheter is in place and while under fluoroscopy, inject a small amount of contrast medium into the coronary sinus to confirm proper placement of the guiding catheter tip in the coronary sinus. The contrast agent will flow out of the coronary sinus.

Once the position is confirmed, use a minimum amount of contrast to identify the coronary sinus branch vein. Save the acquired venogram for future reference of the venous anatomy.

Notes:

- *At the physician's discretion an occlusion balloon catheter may be used. Inflate the balloon to the recommended volume. Inject the contrast medium through the injection port to opacify the sinus and the distal venous branches. Immediately deflate the balloon after the venogram is obtained.*
- *The type, amount, and rate of injection of the contrast medium must be determined by the physician's medical judgment regarding the adequacy of the venogram obtained.*

Placing the Lead

The following section describes two preferred methods for the EASYTRAK lead placement after the guiding catheter has

been positioned in the coronary sinus and a venogram has been obtained.

Notes:

- *The guiding catheter helps to advance the lead into the venous system and can help protect the EASYTRAK lead during the placement of other leads.*
- *To prevent blood from clotting in the lead, Guidant recommends flushing the inner lumen of the lead and the guide wire's protective hoop with heparinized saline* ***before and during*** *guide wire use.*

Method A

1. Insert the 0.014-in (0.36-mm) diameter guide wire into the guiding catheter and advance the tip of the wire through the coronary sinus to the desired position within the venous system.
2. Insert the proximal end of the guide wire into the distal opening of the lead. While holding the guide wire in place, advance the lead over the wire to the desired lead position.

Method B

1. Insert the 0.014-in (0.36-mm) diameter guide wire into the lead. Extend less than 2 cm of the guide wire beyond the distal tip of the lead to ensure the guide wire slides easily through the lumen. Retract the guide wire fully into the lead tip prior to introduction into the guiding catheter.
2. Insert the lead/guide wire assembly into the guiding catheter. Under fluoroscopy, verify the tip of the lead has emerged from the guiding catheter. Advance the guide wire through the coronary sinus to the desired position within the venous system.
3. While holding the guide wire in place, advance the lead over the wire to the desired lead position.

CAUTIONS:

- Use fluoroscopy to verify the guide wire does not prolapse and catch on the distal tip of the lead. If this

occurs, slowly extend the wire beyond the distal tip to free the guide wire and then retract it to reestablish movement of the guide wire.

- If the guide wire cannot be retracted, withdraw the lead/guide wire assembly through the guiding catheter. Remove the guide wire through the distal tip of the lead and reintroduce the lead using a new guide wire. Follow the positioning procedures previously discussed.

Evaluating Lead Position

Verify electrical performance of the lead using a pacing system analyzer or similar monitor before attaching the lead to the pulse generator. Threshold measurements can be taken immediately after the lead is positioned.

Once the lead is placed in the desired location, partially withdraw the guide wire tip into the pacing lead so it does not extend beyond the lead tip. Perform the following measurements. If the results are unsatisfactory, lead system repositioning or replacement may be required.

Perform the following measurements:

- Voltage threshold at 0.5 ms pulse width
- R-wave amplitude
- Pacing impedance

Table 6. Recommended Threshold and Sensing Measurements

Ventricular Data	
Voltage threshold[1]	≤ 3.0 V
R-wave amplitude	≥ 5.0 mV
Lead Impedance	300-1200 Ω

1. Pulse width setting 0.5 ms.

Repositioning the Lead

If the measurements do not conform to these values, fully reinsert the guide wire and reposition the lead using the positioning procedures previously discussed. Verify that measurements are appropriate.

Removing the Guiding Catheter

Once the lead is positioned, remove the guide wire. Next, remove the EASYTRAK Finishing Wire from its protective tube by grasping the finishing wire and pulling the proximal end from the outer protective tube. Unclip the wire from the white retainers. Push the wire into the ring so the distal end exits the hole in the ring, underneath the outer tube. Using short strokes, carefully insert the distal end of the finishing wire into the lead until resistance is felt and the terminal pin reaches the appropriate insertion marker on the finishing wire. If necessary, use clockwise rotations to facilitate finishing wire insertion.

Peel away the introducer sheath, if used. While holding the lead and finishing wire in place, use short, gentle strokes to remove the guiding catheter. Verify under fluoroscopy that the lead has not moved.

Next, hold the proximal end of the lead near the venous entry site and withdraw the finishing wire. Allow extra slack in the lead in the atrium for a strain relief to reduce the chance of dislodgment.

CAUTIONS:

- Do not bend the finishing wire or rotate it counterclockwise in the lead. Counterclockwise rotations or bends in the finishing wire could lock it in the lead or damage the conductor coil.
- If the finishing wire cannot be retracted from the lead, withdraw the lead and finishing wire together. Do not implant with the finishing wire inside the lead.

Securing the Lead

After the lead is satisfactorily positioned, use the following steps to secure the lead to the vein to achieve permanent hemostasis and lead stabilization. An attachable suture sleeve is provided for this purpose.

Venous Cut-Down Technique

1. Place the suture sleeve over the lead body. Slide the suture sleeve into the vein. Ligate the vein around the suture sleeve to obtain hemostasis (Figure 4).

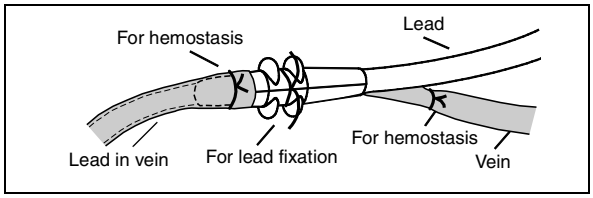

Figure 4. Securing lead with a suture sleeve.

2. Secure a suture around the suture sleeve, then suture the sleeve to adjacent fascia to prevent lead movement. Placing the suture around the suture sleeve prior to suturing to tissue reduces the risk of tissue necrosis caused by a tight suture, which increases the security of the ligature.
3. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

Note: *If venous entry is made using a lead introducer, ligate the lead to the adjacent fascia using the suture sleeve to prevent lead movement.*

Percutaneous Implant Technique

Place the suture sleeve over the lead body. Slide the suture sleeve deep into the tissue. Refer to the Venous Cut-Down Technique section above for information on securing the suture sleeve.

CAUTION: When ligating the vein, avoid too tight a ligature. A tight ligature might damage the silicone rubber insulation or sever the vein. Avoid dislodging the lead tip during the stabilizing procedure.

Connection to a Pulse Generator

When the lead is secured at the venous entry site, reverify position and threshold measurements and then connect the

lead to the pulse generator using the procedure described in the applicable pulse generator physician's manual.

CAUTIONS:

- Do not kink, twist, or braid the lead terminal with other leads, as doing so could cause lead insulation abrasion or conductor damage.
- Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage.

Notes:

- *Guidant suggests using sterile water if a lubricant is needed when connecting the lead to the pulse generator.*
- *If the lead terminal pin will not be connected to a pulse generator at the time of lead implantation, the lead connector must be capped before closing the pocket incision. The LV-1 lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.*

Giving consideration to patient anatomy and pulse generator size and motion, gently coil any excess lead and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure.

Returning Explanted Products

Return all explanted leads to Guidant. Examination of explanted leads can provide information for continued improvement in system reliability. Use a Guidant Returned Product Kit to properly package the lead and complete an Observation/Complication/Out-of-Service Report form. Send the form and kit to Guidant at the address on the back of this manual.

Note: *Disposal of explanted devices is subject to local, state, and federal regulations. Contact your Guidant representative or call Guidant at the telephone number on the back of the manual for a Returned Product Kit.*

REFERENCES

1. LV-1 refers to the Guidant LV™ proprietary connector.
2. Magney JE, et al. Anatomical mechanisms explaining damage to pacemaker leads, defibrillator leads, and failure of central venous catheters adjacent to the sternoclavicular joint. PACE. 1993;16:445-457.
3. Magney JE, et al. A new approach to percutaneous subclavian venipuncture to avoid lead fracture or central venous catheter occlusion. PACE. 1993;16:2133-2142.

SPECIFICATIONS (NOMINAL)

Model	4510/4511/4512/4513
Length	4510 - 65 cm 4511 - 72 cm 4512 - 80 cm 4513 - 90 cm
Terminal compatibility	(1) LV-1
Electrode configuration	Single
Compatibility	Pulse generators that accept LV-1 connectors
Recommended introducer size[1]	8 Fr or larger
Steroid	0.7 mg dexamethasone acetate
Conductors:	
Conductor type	Trifilar coil
Conductor material	Platinum clad tantalum
Electrode:	
Electrode surface area	3.5 mm^2
Electrode material	Platinum iridium
Lead Body:	
Lead body (distal) diameter	1.58 mm (4.8 Fr)
Lead body insulation material	Silicone rubber
Lead body protective sleeve material	Polyurethane
Tines:	
Number of tines	2
Angle of tine projection	45 degrees
Angle of tine separation	180 degrees
Tine material	Silicone rubber

1. Introducer size is determined by guiding catheter size.

GUIDANT

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